

Center for Medicaid and State Operations/Survey and Certification Group

Ref: S&C-05-42

DATE: August 18, 2005

TO: State Survey Agency Directors

FROM: Director
Survey and Certification Group

SUBJECT: **Hospitals** - Revisions to Interpretive Guidelines for Centers for Medicare & Medicaid Services Hospital Conditions of Participation 42 CFR §§482.12, 482.13, 482.27 and 482.28

Letter Summary

This letter provides notice of revisions and clarifications to the Interpretive Guidelines for the Medicare Hospital Conditions of Participation in 42 CFR §482. The revisions provide clarification to issues related to:

- Physician supervision of patients admitted by midwives;
- Grievance process, grievance definition, and grievance responses;
- Availability of emergency laboratory services; and
- Ordering therapeutic diets.

The revisions included in this memorandum provide clarification of Centers for Medicare & Medicaid (CMS) requirements in four Conditions of Participation (CoPs) in 42 CFR §482. They are:

- **Governing Body (§482.12)** - Provides clarification regarding which patients admitted by nurse midwives require physician supervision;
- **Patients' Rights (§482.13)** - Provides clarification of the patient grievance process, revises the definition of grievance, and clarifies requirements for the provision of a written response;
- **Laboratory Services (§482.27)** - Clarifies CMS requirements for the availability of emergency laboratory services; and
- **Food and Dietetic Services (§482.28)** - Clarifies that therapeutic diets must be prescribed (ordered) by the person responsible for the care of the patient.

These changes will be incorporated in ASPEN within 30 days of release of this letter. Revisions to the Appendix A of the State Operations Manual are under way. In the meantime, surveyors are to refrain from writing citations based on previous guidance where that guidance conflicts with these revisions. The revised guidelines are attached to this letter.

Questions regarding these revisions can be addressed to David Eddinger at (410) 786-3429 or email at david.eddinger@cms.hhs.gov.

Effective Date: September 19, 2005. Please ensure that all appropriate staff are fully informed within 30 days of the date of this memorandum, and disseminate the information to affected providers.

Training: The information contained in this announcement should be shared with all hospital surveyors and supervisors.

/s/
Thomas E. Hamilton

cc: Survey and Certification Regional Office Managers (G-5)

Attachment

A-0019

§482.12(c)(2) continued

If a Medicare patient is admitted by a practitioner not specified in paragraph (c)(1) of this section, that patient is under the care of a doctor of medicine or osteopathy.

Interpretive Guidelines §482.12(c)(2)

CMS hospital regulations do permit licensed practitioners (e.g., nurse practitioners, *PAs*, etc), as allowed by the State, to admit patients to a hospital, and CMS does not require these practitioners be employed by a MD/DO. However, CMS regulations do require that Medicare and Medicaid patients admitted by these practitioners be under the care of an MD/DO. Evidence of being under the care of an MD/DO must be in the patient's medical record. If a hospital allows these practitioners to admit and care for patients, as allowed by State law, the governing body and medical staff would have to establish policies and bylaws to ensure that the requirements of 42 CFR §482 are met.

Midwife Patients

42 CFR §482.1(a)(5) states "Section 1905(a) of the Act provides that 'medical assistance' (Medicaid) payments may be applied to various hospital services. Regulations interpreting those provisions specify that hospitals receiving payment under Medicaid must meet the requirements for participation in Medicare (except in the case of medical supervision of nurse midwife services. (See §§440.10 and 440.165 of this chapter)."

Midwives are not specified in 42 CFR §482.12(c)(1).

§482.1(a)(5), when taken with this requirement (42 CFR §482.12(c)(2)) means that in a state that permits midwives to admit patients (and in accordance with hospital policy and practitioner privileges), CMS requires ONLY Medicare patients of a midwife be under the care of a doctor of medicine or osteopathy. CMS DOES NOT require Medicaid or other non-Medicare patients admitted by a midwife be under the care of a doctor of medicine or osteopathy.

Survey Procedures §482.12(c)(2)

If the hospital grants admitting privileges to these practitioners, select *samples of Medicare and Medicaid patients (select only Medicare patients for midwives)* that are admitted to the hospital by these practitioners. Determine if the patient is/was under the care of an MD/DO.

A-0041

§482.13(a)(2) The hospital must establish a process for prompt resolution of patient grievances and must inform each patient whom to contact to file a grievance.

Interpretive guidelines §482.13(a)(2)

The patient should have reasonable expectations of care and services and the facility should address those expectations in a timely, reasonable, and consistent manner. Although §482.13(a)(2)(ii) and (iii) address documentation of facility time frames for a response to a grievance, the expectation is that the facility will have a process to comply with a relatively minor request in a more timely manner than a written response. For example, a change in bedding, housekeeping of a room, and serving preferred food and beverages may be made relatively quickly and would not usually be considered a “grievance” and therefore would not require a written response.

The hospital must inform the patient and/or the patient’s representative of the internal grievance process, including whom to contact to file a grievance (complaint). As part of its notification of patient rights, the hospital must provide the patient or the patient’s representative a phone number and address for lodging a grievance with the State agency.

The hospital must inform the patient that he/she may lodge a grievance with the State agency (the State agency that has licensure survey responsibility for the hospital) directly, regardless of whether he/she has first used the hospital’s grievance process.

*A “**patient grievance**” is a written or verbal complaint (when the verbal complaint about patient care is not resolved at the time of the complaint by staff present) by a patient, or the patient’s representative, regarding the patient’s care, abuse or neglect, issues related to the hospital’s compliance with the CMS Hospital Conditions of Participation (CoP), or a Medicare beneficiary billing complaint related to rights and limitations provided by 42 CFR §489.*

- “**Staff present**” includes any hospital staff present at the time of the complaint or who can quickly be at the patient’s location (i.e. nursing, administration, nursing supervisors, patient advocates, etc.) to resolve the patient’s complaint.*
- If a verbal patient care complaint cannot be resolved at the time of the complaint by staff present, is postponed for later resolution, is referred to other staff for later resolution, requires investigation, and/or requires further actions for resolution, then the complaint is a grievance for the purposes of these requirements. A complaint is considered resolved when the patient is satisfied with the actions taken on their behalf.*
- Billing issues are not usually considered grievances for the purposes of these requirements. However, a Medicare beneficiary billing complaint related to rights and limitations provided by 42 CFR §489 are considered a grievance.*
- A written complaint is always considered a grievance, whether from an inpatient, outpatient, released/discharged patient or their representative regarding the patient care*

provided, abuse or neglect, or the hospital's compliance with CoPs. For the purposes of this requirement an Email or fax is considered "written".

- Information obtained with patient satisfaction surveys does not usually meet the definition of a grievance. If an identified patient writes or attaches a written complaint on the survey and requests resolution, then the complaint meets the definition of a grievance. If an identified patient writes or attaches a complaint to the survey but has not requested resolution, the hospital must treat this as a grievance if the hospital would usually treat such a complaint as a grievance.*
- Patient complaints that become grievances also include situations where a patient or a patient's representative telephones the hospital with a complaint regarding their patient care or with an allegation of abuse or neglect, or failure of the hospital to comply with one or more CoPs, or other CMS requirements. Those post-hospital verbal communications regarding patient care that would routinely have been handled by staff present if the communication had occurred during the stay/visit are not required to be defined as a grievance.*
- All verbal or written complaints regarding abuse, neglect, patient harm or hospital compliance with CMS requirements, are to be considered a grievance for the purposes of these requirements.*
- Whenever the patient or the patient's representative requests their complaint be handled as a formal complaint or grievance or when the patient requests a response from the hospital, then the complaint is a grievance and all the requirements apply.*

Data collected regarding patient grievances, as well as some other complaints that are not defined as grievances (as determined by the hospital) must be incorporated in the hospital's Quality Assessment and Performance Improvement Program (QAPI).

Survey Procedures §482.13(a)(2)

- Review the hospital's policies and procedures to assure that its grievance process encourages all personnel to alert appropriate staff concerning any patient grievance. Does the hospital adhere to its policy/procedure established for referrals?
- Interview patients or the patient's legal representative to determine if they know how to file a complaint (grievance) and who to contact if they have a complaint (grievance).
- Is the hospital following its grievance policies and procedures?
- Does the hospital's process assure that grievances involving situations or practices that place the patient in immediate danger, are resolved in a timely manner?
- Does the patient or the patient's representative know that he/she has the right to file a complaint with the State agency as well as or instead of utilizing the hospital's grievance process?

- Has the hospital provided the telephone number for the State agency to all patients/patient representatives?
- Are beneficiaries aware of their right to seek review by the *Quality Improvement Organization (QIO)* for quality of care issues, coverage decisions, and to appeal a premature discharge?

A-0042

§482.13(a)(2) continued

The hospital's governing body must approve and be responsible for the effective operation of the grievance process, and must review and resolve grievances, unless it delegates the responsibility in writing to a grievance committee.

Interpretive Guidelines §482.13(a)(2)

The hospital's grievance process must be approved by its governing body. The hospital's governing body is responsible for the effective operation of the grievance process, which includes the hospital's compliance with all the CMS grievance process requirements. The hospital's governing body must review and resolve grievances, unless it delegates this responsibility in writing to a grievance committee. A committee is more than one person. The committee membership must have adequate numbers of qualified members to review and resolve the grievances the hospital receives (this includes providing written responses) in a manner that complies with the CMS grievance process requirements.

Survey Procedures §482.13(a)(2)

- Determine if the hospital's governing body approved the grievance process?
- Is the governing body responsible for *reviewing and resolving grievances*, or has the governing body delegated the responsibility in writing to a grievance committee?
- Determine how effectively the grievance process works. Are patient's or the patient representative's concerns addressed in a timely manner? Are patients informed of any resolution to their grievances? Does the hospital apply what it learns from the grievance as part of its continuous quality improvement activities?
- Is the grievance process reviewed and analyzed through the hospital's QAPI process or other mechanism that provides oversight of the grievance process?

A-0043

§482.13(a)(2) continued

The grievance process must include a mechanism for timely referral of patient concerns regarding quality of care or premature discharge to the appropriate Utilization and Quality Control, Quality Improvement Organization. At a minimum:

Interpretive Guidelines §482.13(a)(2)

Quality Improvement Organizations (QIO) are CMS contractors charged with reviewing the appropriateness and quality of care rendered to Medicare beneficiaries in the hospital setting. The QIOs are also tasked with reviewing utilization decisions. Part of this duty includes reviewing discontinuation of stay determinations based upon a beneficiary's request. The regulations state the functions of the QIOs in order to make Medicare beneficiaries aware of the fact that if they have a **complaint regarding quality of care**, disagree with a **coverage decision**, or they wish to appeal a premature discharge, they may contact the QIO to lodge a complaint. The hospital is required to have procedures for referring Medicare beneficiary concerns to the QIOs; additionally, CMS expects coordination between the grievance process and existing grievance referral procedures so that beneficiary complaints are handled timely and referred to the QIO at the beneficiary's request.

This regulation requires coordination between the hospital's existing mechanisms for utilization review notice and referral to QIOs for Medicare beneficiary concerns (See 42 CFR part 489.27). This requirement does not mandate that the hospital automatically refer each Medicare beneficiary's grievance to the QIO; however, the hospital must inform all beneficiaries of this right, and comply with his or her request if the beneficiary asks for QIO review.

Medicare patients have the right to appeal a premature discharge (see Interpretive Guidelines for §482.13(a)). Pursuant to 42 CFR §412.42(c)(3), a hospital must provide a hospital-issued notice of noncoverage (HINN) to any fee-for-service beneficiary that expresses dissatisfaction with an impending hospital discharge. MA organizations are required to provide enrollees with a notice of noncoverage, known as the Notice of Discharge and Medicare Appeal Rights (NODMAR), only when a beneficiary disagrees with the discharge decision or when the MA organization (or hospital, if the MA organization has delegated to it the authority to make the discharge decision) is not discharging the enrollee, but no longer intends to cover the inpatient stay.

Survey Procedures §482.13(a)(2)

- Review patient discharge materials. Is the hospital in compliance with 42 CFR §489.27?
- Does the hospital grievance process include a mechanism for timely referral of Medicare patient concerns to the QIO? What time frames are established?
- Interview Medicare patients. Are they aware of their right to appeal premature discharge?

A-0044

§482.13(a)(2)(i) The hospital must establish a clearly explained procedure for the submission of a patient's written or verbal grievance to the hospital.

Interpretive Guidelines §482.13(a)(2)(i)

The hospital's procedure for a patient or the patient's representative to submit written or verbal grievances must be clearly explained. The patient or patient's representative should be able to clearly understand the procedure.

Survey Procedures §482.13(a)(2)(i)

- Review the information provided to patients *that explains* the hospital's grievance procedures. Does it clearly explain how the patient is to submit either a verbal or written grievance?
- Interview patients or patient representatives. Does the patient, or (if he/she is incapacitated) his/her representative, know about the grievance process and how to submit a grievance?

A-0045

§482.13(a)(2)(ii) The grievance process must specify time frames for review of the grievance and the provision of a response.

Interpretive Guidelines §482.13(a)(2)(ii)

The hospital must review, investigate, and resolve each patient's grievance within a reasonable time frame. For example, grievances about situations that endanger the patient, such as neglect or abuse, should be reviewed immediately, given the seriousness of the allegations and the potential for harm to the patient(s). However, regardless of the nature of the grievance, the hospital should make sure that it is responding to the substance of each grievance while identifying, investigating, and resolving any deeper, systemic problems indicated by the grievance.

Occasionally a *grievance* is complicated and may require an extensive investigation. *We recognize that staff scheduling as well as fluctuations in the numbers and complexity of grievances can affect the timeframes for the provision of written responses. On average, a* timeframe of 7 days for the provision of the response would be considered appropriate. We do not require that *every* grievance be resolved during the specified timeframe although most should be resolved. The Code of Federal Regulations at 42 CFR §482.13(a)(2)(iii) specifies information the hospital must include in their response.

If the grievance will not be resolved, or if the investigation is not or will not be completed within 7 days, the hospital should inform the patient or the patient's representative that the hospital is still working to resolve the grievance and that the hospital will follow-up with a written response within a stated number of days in accordance with each hospital's grievance policy. The hospital must attempt to resolve all grievances as soon as possible.

Survey Procedures §482.13(a)(2)(ii)

What time frames are established to review and respond to patient grievances? Are these time frames clearly explained in the information provided to the patient that explains the hospital's grievance process? *On average, for most months does the hospital provide a written response to most of its grievances within 7 days?*

A-0046

§482.13(a)(2)(iii) In its resolution of the grievance, the hospital must provide the patient with written notice of its decision that contains the name of the hospital contact person, the steps taken on behalf of the patient to investigate the grievance, the results of the grievance process, and the date of completion.

Interpretive Guidelines §482.13(a)(2)(iii)

The written notice of the hospital's determination regarding the grievance must be communicated appropriately to the patient or the patient's representative in a language and manner the patient or the patient's representative understands.

The hospital may use additional tools to resolve a grievance, such as meeting with the patient and his family, or other methods it finds effective. The regulatory requirements for the grievance process are minimum standards, and do not inhibit the use of additional effective approaches in handling patient grievances. However, in all cases the hospital must provide a written notice (response) to each patient's grievance(s). The written response must contain the elements listed in this requirement.

When a patient communicates a grievance to the hospital via email the hospital may provide its response via email pursuant to hospital policy. (Some hospitals have policies against communicating to patients over email.) If the patient requests a response via email, the hospital may respond via email. In these circumstances and when the email response contains the information stated in this requirement, the email meets the requirement for a written response. The hospital must maintain evidence of its compliance with these requirements.

A grievance is considered resolved when the patient is satisfied with the actions taken on their behalf.

There may be situations where the hospital has taken appropriate and reasonable actions on the patient's behalf in order to resolve the patient's grievance and the patient or the patient's representative remains unsatisfied with the hospital's actions. In these situations the hospital may consider the grievance closed for the purposes of these requirements. The hospital must maintain documentation of its efforts and demonstrate compliance with CMS requirements.

In its written response, the hospital is not required to include statements that could be used in a legal action against the hospital, but the hospital must provide adequate information to address each item stated in this requirement. The hospital is not required to provide an exhaustive explanation of every action the hospital has taken to investigate the grievance, resolve the grievance or other actions taken by the hospital.

Survey Procedures §482.13(a)(2)(iii)

Review the hospital's copies of written notices (responses) to patients. Are all patients provided a written *response*? Do the *written responses* comply with the requirements?

A-0284

§482.27 Condition of Participation: Laboratory Services

(a) The hospital must maintain, or have available, adequate laboratory services to meet the needs of its patients. The hospital must ensure that all laboratory services provided to its patients are performed in a facility certified in accordance with Part 493 of this chapter.

Interpretive Guidelines §482.27(a)

The hospital must maintain or have available laboratory services whenever its patients need those services. The hospital may make laboratory services available *directly*, through contractual agreements, *or through a combination of direct and contractual services*. The scope and complexity of the hospital laboratory service must be adequate to meet the needs of its patients. *The hospital must maintain, or have available, adequate laboratory services to meet the needs of its patients at each location of the hospital.* All laboratory services, whether direct or contractual, whether conducted in a lab or in another location, must be provided in accordance with Clinical Laboratory Improvement Act (CLIA) requirements. Every hospital laboratory service must be operating under a current CLIA certificate appropriate to the level of services performed.

The hospital's laboratory services, including any contracted services, must be integrated into its hospital-wide QAPI program.

Patient laboratory results and all other laboratory clinical patient records are considered patient medical records and the hospital must comply with the requirements of the Medical Records CoP.

Survey Procedures §482.27(a)

- Determine the total number of laboratories, the location of each laboratory, and every location where laboratory procedures are performed.
- Verify that the laboratory service and all laboratory locations are integrated into the hospital-wide QAPI program.
- If laboratory services are contracted, verify that the review of the quality of those services is integrated into the hospital-wide QAPI program.

A-0286

§482.27(b)(1) Emergency laboratory services must be available 24 hours a day.

Interpretive Guidelines §482.27(b)(1)

The hospital must provide onsite emergency laboratory services 24 hours a day, 7 days a week. Those onsite emergency services may be provided directly by the hospital or through onsite contracted laboratory services. Emergency lab services include collection, processing, and provision of results to meet a patient's emergency laboratory needs.

In a hospital with multiple hospital campuses, these emergency laboratory services must be available onsite 24/7 at each campus.

The medical staff must determine which laboratory services are to be immediately available to meet the emergency laboratory needs of patients who may be currently at the hospital or those patients who may arrive at the hospital in an emergency condition. The emergency laboratory services (procedures, tests, personnel) available *must* reflect the scope and complexity of the hospital's operation and be provided in accordance with Federal and State law, regulations and guidelines and acceptable standards of practice.

In a hospital with off-campus locations the medical staff must determine which, if any, laboratory services must be immediately available to meet the emergency laboratory needs of the patients who are likely to seek care at that location. The emergency laboratory services available must reflect the scope and complexity of the hospital's operation at that location and be provided in accordance with Federal and State law, regulations and guidelines and acceptable standards of practice. The services must be available during the hours of operation of that location.

Survey Procedures §482.27(b)(1)

Review the written description of the emergency laboratory services. Review records (including accession records, worksheets, and test reports) to verify the 24- hour availability of emergency services and that those services are provided when required.

A-0301

§482.28(b)(1) Therapeutic diets must be prescribed by the practitioner or practitioners responsible for the care of the patients.

Interpretive Guidelines §482.28(b)(1)

Therapeutic diets *must* be:

- Prescribed in writing by *the* practitioner *responsible for the patient's care*;
- Documented in the patient's medical record (including *documentation* about the patient's tolerance to the therapeutic diet as ordered); and
- Evaluated for nutritional adequacy.

In accordance with State law and hospital policy, a dietitian may assess a patient's nutritional needs and provide recommendations or consultations for patients but the patient's diet must be prescribed by the practitioner responsible for the patient's care.

Survey Procedures §482.28(b)(1)

Verify that therapeutic diet orders are prescribed and authenticated by the practitioner(s) responsible for the care of the patient.
